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| APPLICATION NO.  | FILING DATE       | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|--|-------------------|----------------------|-----------------------|------------------|
| 10/634,111   | 08/04/2003        | Peter Redinger       | QC-0108 (1502-82)     | 6388             |
| CARTER, DELUCA, FARRELL & SCHMIDT, LLP<br>445 BROAD HOLLOW ROAD<br>SUITE 225<br>MELVILLE, NY 11704 |                   |                      | EXAMINER              |                  |
|  |                   |                      | KOHARSKI, CHRISTOPHER |                  |
|  |                   |                      | ART UNIT              | PAPER NUMBER     |
|  |                   |                      | 3763                  |                  |
| SHORTENED STATUTORY PI   | ERIOD OF RESPONSE | MAIL DATE            | DELIVER               | Y MODE           |
| 3 MONTI  | HS.               | 03/06/2007           | PAPER                 |                  |

# Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|   |  | X <i>I</i> /  |  |  |  |  |  |
|---|--|---|--|--|--|--|--|
|   | Application No.  | Applicant(s)  |  |  |  |  |  |
|   | 10/634,111   | REDINGER, PETER   |  |  |  |  |  |
| Office Action Summary   | Examiner   | Art Unit  |  |  |  |  |  |
|   | Christopher D. Koharski  | 3763  |  |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply  | pears on the cover sheet with the c  | orrespondence address   |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tir will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE  | N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133). |  |  |  |  |  |
| Status  |  |   |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 21 Fe  | ebruary 2007.  |   |  |  |  |  |  |
|   | The state of the s |   |  |  |  |  |  |
| 3) Since this application is in condition for allowa  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |   |  |  |  |  |  |
| closed in accordance with the practice under E  | Ex parte Quayle, 1935 C.D. 11, 4   | 53 O.G. 213.  |  |  |  |  |  |
| Disposition of Claims   | •  |   |  |  |  |  |  |
| 4)⊠ Claim(s) <u>1-8,10-17 and 19</u> is/are pending in the application.   |  |   |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |  |   |  |  |  |  |  |
| 5) Claim(s) is/are allowed.   |  |   |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1-8, 10-17 and 19</u> is/are rejected.  |  |   |  |  |  |  |  |
| · — · · · ————  | ,  |   |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/o  | or election requirement.   |   |  |  |  |  |  |
| Application Papers  |  |   |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.  |  |   |  |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |  |   |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |   |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |  |   |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Ex  | xaminer. Note the attached Office  | ∋ Action or form PTO-152.   |  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |  |   |  |  |  |  |  |
| 12)☐ Acknowledgment is made of a claim for foreign a)☐ All b)☐ Some * c)☐ None of:  | n priority under 35 U.S.C. § 119(a   | i)-(d) or (f).  |  |  |  |  |  |
| 1. Certified copies of the priority document  | ts have been received.   |   |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |  |   |  |  |  |  |  |
| 3. Copies of the certified copies of the prior  | rity documents have been receiv  | ed in this National Stage   |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).   |  |   |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |  |   |  |  |  |  |  |
|   |  |   |  |  |  |  |  |
|   |  |   |  |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  |  |   |  |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date  |  |   |  |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)  | 5) Notice of Informal 6) Other:  | Patent Application  |  |  |  |  |  |
| Paper No(s)/Mail Date   |  |   |  |  |  |  |  |

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#### **DETAILED ACTION**

# Response to Amendment

Examiner acknowledges the after final reply filed 2/21/2007, in which claims 9, 18 and 20-26 were cancelled with claims 9 and 18 being written in to amend independent claims 1 and 13.

### Response to Arguments

Applicant's arguments, see remarks, filed 2/21/2007, with respect to the rejection(s) of claim(s) 1-8, 10-17 and 19 under Twardowski et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Lotito et al. (7,090,654).

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-3, 5, 7-8, 13-15 and 17 are rejected under 35 U.S.C 103(a) as being unpatentable over Lotito et al. (7,090,654). Lotito et al. discloses a catheter with occlusion resistant tip.

Regarding claims 1-3, 5, 7-8, 13-15 and 17, Lotito et al. discloses a catheter (10) with an elongated body extending from a proximal end to a distal end adapted for insertion within a blood vessel (col 1, ln 20-25), having a first wall (22) and a second wall (26) that define at least one lumen with inlet and outlet ports (Figures 6-7 and 16-18) the first wall including at least one ridge (228) dimensioned and positioned to engage the interior wall portions of the blood vessel to minimize collapse and attain a helical flow pattern (Figure 16) wherein the extending ridge defines a lateral opening (56) and the ridge defines a further lateral channel (212) formed thereon.

Lotito et al. meets the claim limitations as described above except for a plurality of channels.

In cases like the present, where patentability is said to be based upon particular chosen dimensions or upon another variable recited within the claims (plurality of lateral channels), applicant must show that the chosen variable is critical. As such, the claimed variable appears to be an obvious matter of engineering design choice and thus, while being a difference, does not serve in any way to patentably distinguish the claimed invention from the applied prior art see *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990); *In re Kuhle*, 526 F2d. 553, 555, 188 USPQ 7, 9 (CCPA 1975).

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At the time of the invention, it would have been obvious to add additional lateral channels to aid in the flow redirected profile and break up clots (col 10, ln 4-25). The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Lotito et al.

#### Claim Rejections - 35 USC § 103

Claims 4, 10-12 and 19 are rejected under 35 U.S.C 103(a) as being unpatentable over Lotito et al. in view of Mahurkar (5,374,245). Lotito et al. meets the claim limitations as described above except for multiple lumens and ports disclosed in the wall elements.

Regarding claims 4, 10-12 and 19, Mahurkar teaches an elongated body with multiple ports, lumens, walls and ridges that extend from the walls such that distance of the ridges and lumens is configured to support a vessel wall in the manner claimed (Figures 18-21).

At the time of the invention, it would have been obvious to use the additional lumens and side holes of Mahurkar with the system of Lotito et al. because the addition of the additional lumens and the plural side holes allows for additional flow through the catheter and additional lumens for drug delivery. Moreover it would have been obvious to one having ordinary skill in the art at the time the invention was made to add additional lumens, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art, see *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8 (CA7 1977).

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Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Mahurkar.

### Claim Rejections - 35 USC § 103

Claims 6 and 16 are rejected under 35 U.S.C 103(a) as being unpatentable over Lotito et al. Lotito et al. meets the claim limitations as described above except for the ridge angle of less than 90 degrees.

Regarding claims 6 and 16, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the catheter with a ridge angle of less than 90 degrees, since it has been held the variations in shape were a matter of choice and only involves routine skill in the art. See *In re Dailey*, 357 F.2d 669, 149 USPQ (CCPA 1966).

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 3/5/07

Christopher D. Koharski AU 3763